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**FACSIMILE COVER SHEET**

**TO: David B. Bonham, Esq.  
MAYER, FORTKORT & WILLIAMS, PC**

**Date: 13 February, 2004**

**FROM: Michael J. Moran**

**Number of Pages: 11  
(Including cover page)**

**RE: Our reference: 01572.102  
Your reference: 4020/14**

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February 13, 2004

David B. Bonham, Esq.  
Mayer, Fortkort & Williams, PC  
251 North Avenue West, 2<sup>nd</sup> Floor  
Westfield, NJ 07090

RE: U.S. Patent Application Serial No. 09/914,314  
For: *USE OF BIOADHESIVES AND ADJUVANTS FOR THE MUCOSAL DELIVERY  
OF ANTIGENS*  
Our Reference: PP 01572.102  
Your Reference: 4020/14

Dear David:

Enclosed with the confirmation of this letter is a copy of an Office Action mailed January 28, 2004 for the above-identified application. If possible, please prepare a response for my review prior to April 28, 2004. Please feel free to call me at (510) 923-2969 should you have any questions.

Thank you for your assistance in this matter.

Very truly yours,

CHIRON CORPORATION



Michael J. Moran, Ph.D.  
Corporate Patent Counsel

MJM:mlc  
Encl.



## UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,314	01/08/2002	Manmohan Singh	PP01572.102	2216

7590

01/28/2004

Alisa A Harbin  
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EXAMINER

HILL, MYRON G

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

DOCKETED on/by 2/3/04/ com  
*Examiner cites ref* PA  
 File # PP01572.102  
 Date 4/28/04 Ext R53  
 Date 7/28/04 R50

PTO-90C (Rev. 10/03)

**Office Action Summary**

Application No.

09/914,314

Applicant(s)

SINGH ET AL.

Examiner

Myron G. Hill

Art Unit

1648

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11/17/03 and 12/11/03.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1- 32 is/are pending in the application.
- 4a) Of the above claim(s) 5, 6, and 15- 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1- 4, and 7- 14 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet, 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet, 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) see Action 6) ☐ Other:

Application/Control Number: 09/914,314  
Art Unit: 1648

Page 2

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election of Group I in response filed 3 November 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The election was not complete and a call was made to David Bonham to complete the election of specific product as required in the Lack of Unity. Applicant responded on 11 December 2003 with an election of cross-linked derivatives of poly(acrylic acid) as the bioadhesive.

Claims 5, 6, and 15- 32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

This action is on claims 1- 4 and 7- 14.

### *Information Disclosure Statement*

Two IDS PTO-1449's were filed (22 and 25 October 2002) which cite the same references. One form has been considered and the other has had the references crossed out because they are duplicates.

### *Claim Rejections - 35 USC § 102*

Application/Control Number: 09/914,314  
Art Unit: 1648

Page 3

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7, and 8- 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Duncan *et al.* (WO 94/20070).

Duncan *et al.* teach a composition of a bioadhesive which is a mucoadhesive, an antigen, and an adjuvant in which the ratio of antigen to bioadhesive is about 0.01% to 40% and the ratio of adjuvant to bioadhesive is about 0.01% to 40% (page 12, lines 23- 35 and Examples). Also, Duncan *et al.* teach the use of carbopol or polycarbophil as the poly (acrylic acid) which is the bioadhesive (list on page 8, and Examples), the use of at least one pharmaceutically acceptable excipient (page 10, lines 10- 20), the adjuvant is alum (page 9, line 6), an influenza virus is used as antigen (Examples), and the composition can be provided as a microsphere that is absorbed on a subcoating or is coated by an enteric coating to encapsulate the composition (page 12, lines 2- 11).

Thus, Duncan *et al.* anticipate the claimed invention.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Application/Control Number: 09/914,314  
Art Unit: 1648

Page 4

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 7, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duncan *et al.* and Giuliani *et al.*

Duncan *et al.* teaches a composition comprising an antigen, an adjuvant, and a bioadhesive as discussed above in the rejection of claims 1-4, 7, and 8-14. Duncan *et al.* teach the advantage of bacterially derived adjuvants (Examples 6 and 7).

Duncan *et al.* do not teach LT-R 72.

Giuliani *et al.* teach a modified *E. coli* enterotoxin that has improved properties over wild type enterotoxin, LT-R72 (abstract).

One of ordinary skill in the art at the time of invention would have been motivated to use the adjuvant of Giuliani *et al.* because they teach that it is a mucosal adjuvant, that it is less toxic than wild type and would expect it to work as an adjuvant because it has high adjuvanticity and is shown to function as an adjuvant.

Thus it would have been *prima facie* obvious to modify the composition of Duncan *et al.* with the adjuvant of Giuliani *et al.* with the expectation of success because both are bacterially derived adjuvants.

Therefore, the instant invention is obvious over Duncan *et al.* and Giuliani *et al.*

Application/Control Number: 09/914,314  
Art Unit: 1648

Page 5

**Conclusion**

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure because it discloses more details of microspheres than included in Duncan *et al.* WO 95/11700 (IDS), US 5707644 (IDS), and US 6143211.

Myron G. Hill  
Patent Examiner  
20 January 2004

*James C. Howell*  
1/26/04



SHEET 1 OF 1

FORM PTO-1449 (Modified)	U.S. Dept. of Commerce Patent and Trademark Office	Atty. Docket No.: 1572.102	Serial No.: 097914,314
INFORMATION DISCLOSURE CITATION		Applicants: Singh <u>et al.</u>	
(Use several sheets if necessary)		Filing Date: January 8, 2002	Group: to be assigned

## U.S. PATENT DOCUMENTS


* Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
AA	9-707,644	12/20/80	Ellis			RECEIVED OCT 25 2002 TECH CENTER 1600/2900

## FOREIGN PATENT DOCUMENTS

		Document Number	Publ. Date	Country	Class	Subclass	Trans- Ver	lation No
	BA	JO4.788	08/17/88	Europe				
	BN	WO 94/20070	03/16/94	PCT				
	BC	WO 93/11780	10/28/93	PCT				
	BD	WO 95/17211	06/29/95	PCT				
	BE	WO 98/42375	03/19/98	PCT				

**OTHER CITATIONS (Including Author, Title, Date, Pertinent Pages, Etc.)**

[illegible]

Examiner	Date Considered
	1/20/04

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MFCR 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



**Notice of References Cited**

Application/Control No.

09/914,314

Applicant(s)/Patent  
Reexamination  
SINGH ET AL

Examiner

Myron G. Hill

Art Unit

1648

Page 1 of 1

**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-6,143,211	11-2000	Mathiowitz et al.	264/4
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

**FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)				
	U					
	V					
	W					
	X					

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
 Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

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